



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0571]

Ortho-phthalates for Food Contact Use; Reopening of Comment Period; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice titled “*Ortho-phthalates for Food Contact Use; Request for Information*,” which published in the *Federal Register* of May 20, 2022. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested parties to develop and submit data, other information, and comments for this request for information.

DATES: FDA is reopening the comment period on the notice “*Ortho-phthalates for Food Contact Use; Request for Information*,” which published in the *Federal Register* on May 20, 2022 (87 FR 31090). Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-0571 for "Ortho-phthalates for Food Contact Use; Reopening of the Comment Period; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jessica Urbelis, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5187; or Meadow Platt, Office of Regulations and Policy (HFS-024),

Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr.,
College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 20, 2022 (87 FR 31090), FDA published a notice with a 60-day comment period to request data and information on the current food contact uses, use levels, dietary exposure, and safety data on any *ortho*-phthalates currently used in food contact applications. We originally gave interested persons until July 19, 2022, to provide data and information.

Following publication of the notice, FDA received a request to allow interested parties additional time to comment. The request asserted that 60 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues and requested that FDA extend the comment period by an additional 6 months. We have considered this request and, because the request came too late for us to extend the comment period before it expired, we are reopening the comment period for 90 days. FDA believes that this additional 90 days will allow time for interested parties to submit data and other information to support our review of the current use levels and safe use of certain *ortho*-phthalates in food contact applications.

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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